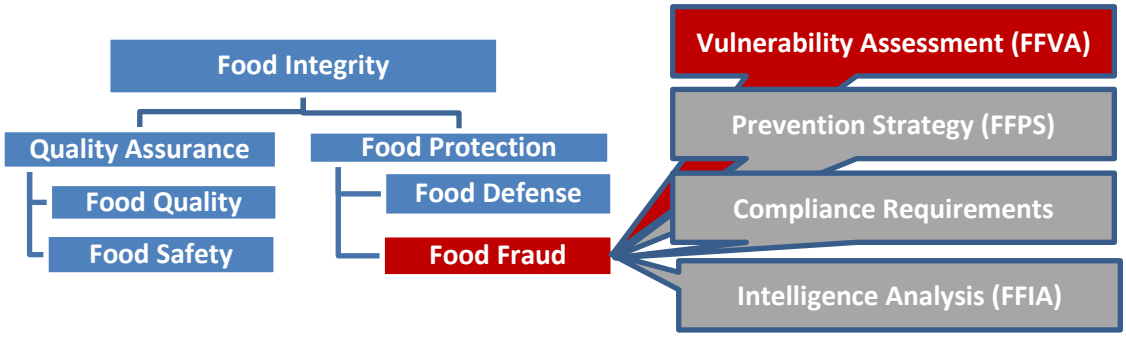
Food Fraud Prevention Think Tank

Primer on Food Fraud Vulnerability Assessment (FFVA) **MAY 2020**



Food Fraud Vulnerability Assessment (FFVA) –

An evaluation of the susceptibility of a system to food fraud.[i]

This Primer presents a strategy and hierarchy for FFVA compliance. There are standardized methods that are free and published in scholarly journals. Completing the FFVA for your entire company and all products is critical and already implicitly a compliance requirement in the Food Drug & Cosmetics Act of 1938 ('Adulterated Foods' and 'Misbranded Foods') and Sarbanes-Oxley Act of 2002 (manage or report risks to revenue or equity). While the Food Safety Modernization Act (FSMA) may not explicitly require an FFVA to pass inspection, after an incident during an investigation, a logical question could be "how did you define this NOT to be a 'hazard that required a preventive control." If there is a death or severe illness, the lack of a method could be – literally – criminal.

This 'Primer' covers Food Fraud Vulnerability Assessment models or tools and not incident databases or monitoring systems. The Primer includes links to free or open Intellectual property tools and methods.

Food Fraud is illegal deception for economic gain using food – this includes the FDA defined sub-category of economically motivated adulteration (EMA).[ii] This covers all types of fraud (including stolen goods, tampering, and counterfeiting) and all products (from raw ingredient materials to finished goods at retail).[iii]

The first step in Food Fraud prevention is assessing the situation. The result of a vulnerability assessment is usually a qualitative statement of the susceptibility of the system. A *vulnerability* and *threat* combine to define a *risk*. The threshold determines *acceptable* or *unacceptable* levels of risk. The unacceptable risk would be an FDA defined 'hazard that requires a preventive control.' Not all vulnerabilities are unacceptable risks. For compliance, every vulnerability must be assessed to define what is ***NOT*** a 'hazard that requires a preventive control.'

FFVA Requirements: Specifically the Global Food Safety Initiative (GFSI) requires a documented Food Fraud Vulnerability Assessment method as of January 1, 2018. While the Food Fraud focus has been on the GFSI activities conducting an FFVA (or a review of hazards) has implicitly been a requirement since the Food Drug & Cosmetics Act of 1938 (FDCA). FDCA defines acts that are illegal acts regardless of whether there is a health hazard or not (re. Adulterated Foods and Misbranded Foods). Also, the Sarbanes-Oxley Act of 2002 requires *Internal Controls/ Integrated* framework for managing risk to revenue and equity.

Hierarchy of Assessments: As with any risk assessment or vulnerability assessment, it is conducted within an enterprise-wide definition of what is *acceptable* or *unacceptable*. This applies to governments or companies. To begin, standard assessments – such as the SSAFE/GFSI tool[iv], US Pharmacopeia Food Fraud Mitigation Guide[v], or the Food Fraud Initial Screening Tool (FFIS)[vi] – set a general risk threshold. The risk thresholds are qualitative statements of "very high" to "very low." There is often not enough data to conduct a statistically significant probability for the marketplace – complex quantitative, analytical assessments on the available data can lead to overconfidence since they reveal insights from the available data (Figure 1).

1. ***Corporate Risk Appetite[vii]:*** Unless there is a limit set by regulations the threshold of acceptable is defined by the stakeholders (usually the Risk Committee of the Board of Directors and implemented by the CEO/CFO). This fluctuates over time. This is a regulatory requirement of the Sarbanes-Oxley Act by the Committee of the Sponsoring Organization of the Treadway Commission (COSO).
2. ***Enterprise Risk Management ERM[viii]:*** An ERM or ERM-like internal controls and integrated framework is a method to manage and monitor all risks across the entire enterprise. For efficiency and competence, the risk or vulnerability assessments should be presented in ERM terms.
3. ***Assessment—Initial Screening (Pre-filter)[ix]:*** This 'Stage 1' of the COSO/ERM defined assessments. This can be extremely quick and brief. The objective is a first view of the entire issue. This can be conducted for broad product groups and major regions but it must cover ALL types of fraud and ALL products. Presented here is the Food Fraud Initial Screening Tool (FFIS).[vi] The GFSI compliance requires addressing ALL vulnerabilities not necessarily EACH item – products can be grouped.

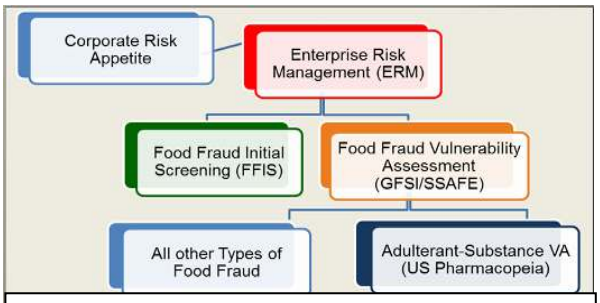


Figure 1: Hierarchy of Food Fraud Decision-Making and Vulnerability Assessments

4. ***Assessment--Detailed Assessment (Vulnerability Assessment)[x]:*** The resource-allocation decision-maker – either directly or through policy statements – defines how much additional detail is needed for the current decisions. In many cases, the FFIS is enough for early decisions. In other situations, an FFVA may be required for individual supplier facilities and each product.
5. ***Assessment—Adulterant-Substance Detail[xi]:*** Additional levels of detail may be optimal for specific fraud types or products. For example, the US Pharmacopeia (USP) developed a Food Fraud Mitigation Guide for food fraud ingredient adulterant-substances
6. ***Assessment—Other:*** As the Food Fraud Prevention Strategy (FFPS) implemented there may be additional specific needs. This could include ISO 28000 Supply Chain Security, ISO ISO/CD 19564 Product fraud countermeasures and control, Cargo Theft assessment, a Counterfeit Product Risk Model or others.

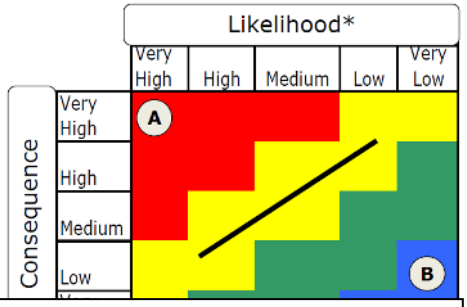


Figure 2:Corporate Risk Map Example of Risk Summing[vi, vii]

Compliance First Step and 'How Much is Enough?' While the FFVA requirements may seem overwhelming – and penalties may seem daunting – there has been quite a bit of policy and strategy research to establish a firm foundation. This Primer has reviewed the hierarchy of Food Fraud Decision-Making. The first steps are very basic. "How much is enough" is defined by your own 'fraud opportunity' in relation to your unique enterprise-wide 'risk appetite.' For the FFVA, the logical first step is to scope the situation by conducting – and documenting – a quick Food Fraud Initial Screening (FFIS). For the next steps see the ***Primer on Food Fraud Prevention Strategy Development*** and then the ***Primer on Food Fraud Intelligence Analysis and Horizon Scanning***.

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[i] Spink, John, Ortega, David, Chen, Chen, and Wu, Felicia (2017). Food Fraud Prevention Shifts Food Risk Focus to Vulnerability, Trends in Food Science and Technology Journal, Volume 0, Number 0, Pages 00-00, http://www.sciencedirect.com/science/article/pii/S0924224416304915
[ii] FDA Public Meeting, 2009: https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm163656.htm
[iii] For more background see the Primer on Food Fraud at www.FoodFraud.msu.edu.
[iv] SSAFE Food Fraud Vulnerability Assessment Tool: http://www.ssafe-food.org/our-projects/
[v] US Pharmacopeia (USP) Food Fraud Mitigation Guide: https://www.usp.org/ffmg-form
[vi] Spink, John, Moyer, Douglas C, & Speier-Pero, Cheri (2016). Introducing the Food Fraud Initial Screening Model (FFIS), Food Control, Volume 69, November 2016, Pages 306-314. https://www.sciencedirect.com/science/article/pii/S0956713516301219
[vii] COSO/ Enterprise Risk Management: https://www.coso.org/Pages/erm-integratedframework.aspx
[viii] See COSO
[ix] See FFIS
[x] See SSAFE
[xi] See USP